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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,258	03/05/2002	David R. Hathaway	P03660US7	8234

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EXAMINER	
LIU, SAMUEL W	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 02/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/091,258	HATHAWAY ET AL.	
	Examiner	Art Unit	
	Samuel W Liu	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☒ Claim(s) *1 and 9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8-8-02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

Claims 1-11 are pending.

The following Office Action is applicable to the pending claims 1-11.

IDS

The references lists in IDS filed 8 August 2002 have been considered.

Specification/Claim/ Objections

The disclosure is objected to because of the following informalities:

(1) In page 11, line 3, "SEQ ID NO 3" should be changed to "SEQ ID NO:3".

(2) In claim 1, "GLP-1" should be fully spelled out for the first recitation in the claims; see also claim 9, "PVD".

Appropriate correction is required.

Claim Rejections - 35 USC § 112, the second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "treating or preventing"; the recitation is unclear as to which process the claimed method is directed, treating or preventing? Note that the pathological mechanism as well as administration route of treatment is different/distinct from that of prevention, absent factual

indicia to the contrary. See also claim 2. The dependent claims are also rejected.

Claim 3 recites "GLP-1 (7-36)NH_2"; the recitation is not apparent as to whether or not it refers to amine group(s) of any lysine side chain(s) or carboxyl terminal amide group. Also, claim 3 is unclear in the recitation "the GLP-1 molecule …., and exendin-4" because exendin-4 is not GLP-1 but rather a GLP-1 analog. Additionally, claim 3 lacks antecedent basis for the limitation "the GLP-1 molecule is selected from the group consisting of GLP-1 (7-36)NH_2, GLP-4 (7-37), and exendin-4' in the claim since said GLP-1 molecule is virtually GLP-1 analog not unmodified GLP-1 molecule. See also claims 4.

Also, Claim 3 is indefinite in "GLP-4 (7-37)" because the specification does not define what the GLP-4 is.

Claim 11 is indefinite in the term "formulation" because the claim does not make it clear as to whether or not said formulation comprises the GLP-1 peptide.

Claim Rejections - 35 USC § 112, the first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification as originally filed does not provide support for the invention as now claimed.

Applicants are not in possession of a method of treating intermittent claudication that is caused by or associated with atherosclerosis-related peripheral vascular disease (PVD).

The specification fails to provide sufficient description regarding how to use GLP-1 or analog thereof, or, exendin-4, for treating intermittent claudication (IC) that is caused by or associated with atherosclerosis-related peripheral vascular disease (PVD). The specification does not provide working example(s) or animal model and guidance regarding ability of GLP-1 or analog thereof (e.g., GLP-1 (7-36)NH_2, see claims 3-4) or exendin-4 peptide treating IC disorder state. In addition, the instant disclosure appears silent in teaching how to make and use a compound termed GLP-4 and analog thereof (see claim 3, GLP-4 (7-37)).

Applicants are not in possession of a method of preventing IC disorder state that is caused by or associated with PVD symptom. The specification does not reasonably provide a written description of how to prevent an intermittent claudication (IC) disorder state using GLP-1 or analog thereof including exendin-4. The instant application provides neither teaching nor working example(s), or animal model, with regard to prevention of the IC state using the above-mentioned GLP-1 or analog thereof.

Application has disclosed only the method of GLP-1 treatment cardiac muscle ischemia disorder state, but not method of GLP-1 treatment or prophylaxis of IC disorder state that is caused by or associated with peripheral vascular disease (PVD). The skilled artisan thus cannot envision all the contemplated GLP-1 treatment of IC disorder state recited in the instant claims. And, the skilled artisan would not know how to extend the result form the treatment of cardiac muscle ischemia to treatment or prophylaxis of IC disorder state thereof. Consequently, conception cannot be achieved until a representative description of such the treatment or

prophylaxis stated above, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC1993).

One of skill in the art would reasonably conclude that the instant disclosure fails to provide written description regarding therapeutic use of GLP-1 or analog thereof as set forth in the claims. Thus, Applicant was not in a possession of using GLP-1 or GLP-1 analog (including exendin-4) for treating or preventing intermittent claudication disorder state.

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

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Samuel Wei Liu, Ph.D.

February 17, 2004